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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Richard E. Stein

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

10/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,093	Applicant(s) STEIN ET AL.	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 41-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 41-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/23/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The affidavit filed on 7/23/08 under 37 CFR 1.131 has been considered but is ineffective to overcome the Musley reference since ALL the named inventors must have completed an affidavit to overcome the rejection. (See MPEP 715.04).

In addition, in general, proof of actual reduction to practice requires a showing that the apparatus actually existed and worked for its intended purpose. For an actual reduction to practice, the invention must have been sufficiently tested to demonstrate that it will work for its intended purpose, but it need not be in a commercially satisfactory stage of development. >See, e.g., Scott v. Finney, 34 F.3d 1058, 1062, 32 USPQ2d 1115, 1118-19 (Fed.Cir. 1994)(citing numerous cases wherein the character of the testing necessary to support an actual reduction to practice varied with the complexity of the invention and the problem it solved). Only drawings showing the outline and appearance of the device have been presented. These drawings do not provide proof or evidence to show that the system actually was produced or tested..

Election/Restrictions

Applicant's election without traverse of the telephone restriction in the reply filed on 3/5/08 is acknowledged.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 41 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musley et al (2004/0210256) in view of Tacker, Jr. et al (6006132).

Musley et al discloses the claimed invention as a patient activator having heart rhythm status information such as normal rhythm, abnormal rhythm, therapy pending and contact caregiver indicators (e.g. figure 1, paragraph 40), receiving and displaying the information, and use of a therapy request button to deliver therapy and indicate therapy is pending. Musley does not disclose that it is a handheld device and that in response to the therapy request that the heart rhythm status information is provided. Tacker teaches that it is known to use a handheld activator and to provide the heart rhythm status information in response to the therapy request to provide a device that the patient can easily carry and use and to allow the patient to reconfirm the arrhythmia before the therapy is delivered and to provide the patient with updated status information based on the therapy request (e.g. col 8, lines 22-40). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac device and method as taught by Musley, with the handheld device and that in response to the therapy request that the heart rhythm status information is provided as taught by Tacker, since

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such a modification would provide a cardiac device with a handheld activator device and that in response to the therapy request that the heart rhythm status information is provided to provide the predictable results of a device that the patient can easily carry and use and to allow the patient to reconfirm the arrhythmia before the therapy is delivered and to provide the patient with updated status information based on the therapy request.

Claims 42-45, 47, and 48 rejected under 35 U.S.C. 103(a) as being unpatentable over Musley in view of Tacker as applied to claims 41 and 46 above.

Musley in view of Tacker discloses the claimed invention except for the interface device having a stop therapy button to stop therapy and the interface having deadfront status indicators each with different pictorial graphic shapes, such as a green colored heart shape, orange colored icon in a heart shape with a clock face, a yellow colored icon in the shape of a heart with a sharp jagged line extending across the heart, and a red colored icon in the shape of a telephone having a base unit with a cross in the center of the base unit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac system and method as taught by Musley in view of Tacker, with the interface device having a stop therapy button to stop therapy and the interface having deadfront status indicators each with different pictorial graphic shapes since it was known in the art that cardiac devices and methods use: an interface device having a stop therapy button to stop therapy to provide the predictable results of allowing the patient to stop therapy if they are unprepared for the therapy and/or need to lie down or take a sedative; and the interface having deadfront status indicators each with different pictorial graphic shapes, such as a green colored heart shape, orange colored icon in a heart shape with a clock face, a yellow colored icon in the shape of a heart with a sharp jagged line

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extending across the heart, and a red colored icon in the shape of a telephone having a base unit with a cross in the center of the base unit, to provide the predictable results of: allowing the operator to use their visual sense to determine the status of the device which can aid in noisy environments; allowing the device to clearly indicate the status to allow the operator to easily distinguish between different conditions; allowing caregivers to more quickly and efficiently perform the required steps or to allow caregivers not familiar with that country's language/text to still operate the device and perform the correct steps. In addition, the use of the different shapes, such as set forth in claims 45 and 48, does not patentably distinguish or is of patentable significance over the system and method of Musley in view of Tacker since it is an arbitrary/aesthetic design consideration that is obvious to one having ordinary skill in the art (see MPEP 2144.04).

Response to Arguments

Applicant's arguments filed 7/23/08 have been fully considered but they are not persuasive. The argument that Musley and/or Tacker do not disclose an indication of the heart rate status in response to a therapy request command is not persuasive since Tacker states that the status messages are made available at each stage of the redetection and cardioversion process upon initiating the therapy switch (e.g. col 8, lines 22-40). The argument that the Examiner has not shown the use of dead front status indicators to illustrate heart rhythm status is not persuasive since this limitation has previously been presented and rejected (numerous times), such as in the action of 4/27/07. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight

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reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

GRE
10/26/08